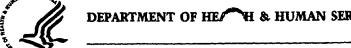
Public Health Service



Food and Drug Administration Rockville MD 20857

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Re: Zevalin Docket No. 02E-0343

The Honorable James E. Rogan Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office Box Pat. Ext. P.O. Box 1450 Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 5,776,456 filed by IDEC Pharmaceuticals Corporation under 35 U.S.C. § 156. The patent claims Zevalin, BLA 1250190.

In the April 21, 2003, issue of the Federal Register (68 Fed. Reg. 19547), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before October 20, 2003, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Associate Director for Policy

Center for Drug Evaluation and Research

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cc: Robin L. Teskin

> Pillsbury Winthrop, L.L.P. 1600 Tyson Boulevard McLean, VA 22102

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